Kidney Transplantation Committee Update

John Friedewald, MD
Chair

Board of Directors
Atlanta, GA
November 15, 2011
Major Efforts

- Kidney Allocation System Revisions
- Variance Review
- Kidney Paired Donation Pilot Program
KIDNEY ALLOCATION SYSTEM

OPTN
Current System Limitations

- Mismatch between potential survival of the kidney and the recipient
- Variability in access to transplantation by blood group and geographic location
- High discard rates of kidneys that could benefit candidates on the waiting list
- Reduce differences in transplant access for populations described in NOTA (e.g., candidates from racial/ethnic minority groups, pediatric candidates, and sensitized candidates).
Path Forward for KAS

- Introduction of elements of allocation
  - Longevity matching
  - Improved waiting time
  - Improved CPRA points
  - Improved access for minority candidates
  - Improved efficiency in placement of kidneys at highest risk of discard
  - Broader sharing for most highly sensitized and for certain types of donated kidneys
Committee Decisions

- **X** age matching
- Longevity matching for top 20%
- A2/A2B nationally
- ESRD time in addition to waiting time
- KDPI
- Sliding scale for CPRA points

- **✓** expedited placement for high KDPI kidneys
- **✓** broader sharing for the most highly sensitized candidates (CPRA >=98%)

Previously proposed and supported

New concepts
Prior Concepts Proposed

- Utilize a kidney donor profile index (KDPI) to better characterize donor kidneys and to provide additional clinical information for patients and providers to consider during the transplant evaluation process and organ offer process.

- Allocate the majority of organs (80%) by age matching so that candidates within 15 years (older and younger) of the donor are prioritized.

- Allocate some kidneys (20%) by a kidney donor profile index (KPDI) and estimated recipient post-transplant survival.
Feedback Received

- General agreement with longevity matching for some kidneys
- Concerns over use of age matching (+/-15 years)
- Support for use of KDPI as a clinical tool and in allocation
Current Working Model

Patients rank ordered by
- Waiting /ESRD time
- DR matching
- Sliding scale CPRA

System features
- A2 -> B

Patients rank ordered by
- Waiting/ESRD time

System features
- Regional sharing
- A2 -> B

Opt in system of highest 15% KDPI kidneys
“Think improved ECD”

Top 20 % KDPI to Top 20 % EPTS

Allocation under “current rules”

KDPI Scale

0--------------------------------20-------------------------------------------------85------------------------100
# Addressing System Limitations

<table>
<thead>
<tr>
<th>Stated Limitation of the Current System</th>
<th>Applicable Concepts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mismatch between potential survival of the kidney and the recipient</td>
<td>Longevity matching</td>
</tr>
<tr>
<td>Variability in access to transplantation by blood group and geographic location</td>
<td>A2/A2B, broader sharing</td>
</tr>
<tr>
<td>High discard rates of kidneys that could benefit candidates on the waiting list</td>
<td>KDPI, expedited placement,</td>
</tr>
<tr>
<td>Reduce differences in transplant access for populations described in NOTA (e.g., candidates from racial/ethnic minority groups, pediatric candidates, and sensitized candidates).</td>
<td>ESRD time, broader sharing, CPRA sliding scale, maintain peds priority</td>
</tr>
</tbody>
</table>
Highlights

- Allocation based on longevity matching is accepted and sustains legal scrutiny
- The majority of kidneys are still allocated very similarly to current rules
- Waiting time remains the primary determinant of kidney allocation with a more inclusive definition
- Improve “ECD” system addresses concerns of older recipients
  - “Opt in” preserves choice
  - Allows trade off of a kidney with more longevity for more rapid transplantation
  - Regional allocation might improve recovery and placement
  - Allocation on time alone makes it predictable and allows list management.
Results from Run 37

Excerpted from November 2009 Report to the Board
## Run 37 vs. Considered

<table>
<thead>
<tr>
<th></th>
<th>Run 37</th>
<th>Considered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Top 20%</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>A2/A2B Nationally</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>ESRD Time</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>HLA-DR Points</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>KDPI</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>CPRA Sliding Scale</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>expedited placement for high KDPI kidneys</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>broader sharing for the most highly sensitized candidates (CPRA &gt;=98%)</td>
<td></td>
<td>x</td>
</tr>
</tbody>
</table>
## Survival Benefit Due to Tx

<table>
<thead>
<tr>
<th></th>
<th>Run 36 Baseline (2009 + Extras)</th>
<th>Run 37 (top 20% to top 20%)</th>
<th>Concept Document (top 20%, then within 15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of transplant recipients</td>
<td>10652</td>
<td>10608</td>
<td>10930</td>
</tr>
<tr>
<td>Total lifespan after tx</td>
<td>119392</td>
<td>137931</td>
<td>140686</td>
</tr>
<tr>
<td>Total graft years of life</td>
<td>81600</td>
<td>87677</td>
<td>97045</td>
</tr>
<tr>
<td>Change in lifespan after transplant (ref)</td>
<td>18540</td>
<td>15,223</td>
<td></td>
</tr>
<tr>
<td>Change in graft years of life (ref)</td>
<td>6077</td>
<td>4,847</td>
<td></td>
</tr>
<tr>
<td>Change in extra years (ref)</td>
<td>6290</td>
<td>5,112</td>
<td></td>
</tr>
</tbody>
</table>

OPTN
Percentage Transplants by Age

- < 18: 5, 5, 5
- 18-34: 11, 16, 18
- 35-49: 27, 28, 31
- 50-64: 41, 36, 35
- 65+: 16, 14, 11

- Run 36 Baseline (2009 + extras)
- Run 37 (top 20% to top 20%)
- Concept Document (top 20%, then within 15)
Percentage Transplants by ABO

- A: 33 33 33
- AB: 5 5 5
- B: 15 15 15
- O: 47 47 47

- Run 36 Baseline (2009 + extras)
- Run 37 (top 20% to top 20%)
- Concept Document (top 20%, then within 15)
Percentage Transplants by Diagnosis

- **Glomerular**: 212324
- **Hypertension**: 222222
- **Polycystic**: 6666
- **Diabetes**: 312826
- **Other/Missing**: 192121

- **Run 36Baseline** (2009 + extras)
- **Run 37** (top 20% to top 20%)
- **Concept Document** (top 20%, then within 15)
Percentage of Transplants by PRA

- Run 36
  - Baseline (2009 + extras)
- Run 37
  - Top 20% to top 20%
- Concept Document
  - Top 20%, then within 15
VARIANCE REVIEW PROCESS
Process to date

- Review of existing variance according to Final Rule requirements
  - Research design
  - Time limited
  - Designed to test potential policy modifications before national implementation

Kidney Committee reviewed all existing variances and identified those that it believed would be beneficial if implemented as part of a national kidney allocation policy.
Next Steps

- Committee will send letters to each OPO regarding its recommendations.

  **Letter #1: Recommendations for national policy**
  OPOs that wish to propose that its variance be reconsidered for national allocation policy will be asked to submit a brief (no more than 2 page) rationale.

  **Letter #2: Recommendations for ALUs/Sharing arrangements**
  OPOs wishing to maintain variances due to unique geographical constraints will be asked to submit a rationale.

*This phase is to be completed by Q1 2012*
Recommendations to Board

The Committee will review any responses to its letters before making final recommendations to the Board of Directors to either:

- incorporate the variance into national kidney allocation policy
- acknowledge that the OPO has a permanent need for an alternative arrangement and codify in policy
- discontinue the variance.

Board will review recommendations in June 2012
Kidney Paired Donation Pilot Program Update
August 2011 Match Run Results

<table>
<thead>
<tr>
<th>Participants included in the match</th>
</tr>
</thead>
<tbody>
<tr>
<td>149 candidates</td>
</tr>
<tr>
<td>158 total donors</td>
</tr>
<tr>
<td>4 NDDs (1 blood type O, 2 blood type B, 1 blood type AB)</td>
</tr>
<tr>
<td>42 centers from 11 regions had at least one eligible pair.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 candidates from 7 regions matched</td>
</tr>
<tr>
<td>Chain with 12 links (1 NDD, 11 pairs, and 1 waiting list candidate)</td>
</tr>
<tr>
<td>Two 3-ways and one 2-way</td>
</tr>
<tr>
<td>7 highly sensitized candidates matched</td>
</tr>
</tbody>
</table>
## Overall Match Run Results

<table>
<thead>
<tr>
<th>Match Run Date</th>
<th>Candidates</th>
<th>Donors</th>
<th>Candidates Matched</th>
<th>Candidates Transplanted</th>
</tr>
</thead>
<tbody>
<tr>
<td>October 27, 2010</td>
<td>43</td>
<td>45</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>December 8, 2010</td>
<td>60</td>
<td>62</td>
<td>12</td>
<td>0</td>
</tr>
<tr>
<td>January 19, 2011</td>
<td>66</td>
<td>69</td>
<td>11</td>
<td>0</td>
</tr>
<tr>
<td>February 23, 2011</td>
<td>76</td>
<td>78</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>March 23, 2011</td>
<td>88</td>
<td>90</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>April 28, 2011</td>
<td>106</td>
<td>109</td>
<td>6</td>
<td>3 scheduled for November</td>
</tr>
<tr>
<td>May 26, 2011</td>
<td>117</td>
<td>124</td>
<td>7</td>
<td>0</td>
</tr>
<tr>
<td>June 21, 2011</td>
<td>132</td>
<td>142</td>
<td>19</td>
<td>3</td>
</tr>
<tr>
<td>July 20, 2011</td>
<td>145</td>
<td>157</td>
<td>19</td>
<td>3</td>
</tr>
<tr>
<td>August 17, 2011</td>
<td>149</td>
<td>158</td>
<td>20</td>
<td>1; 5 scheduled for November</td>
</tr>
<tr>
<td>September 14, 2011</td>
<td>139</td>
<td>148</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>October 18, 2011</td>
<td>130</td>
<td>141</td>
<td>11</td>
<td>3 in crossmatch</td>
</tr>
</tbody>
</table>
### Candidate Characteristics

**Candidates entered in August 2011 Match Run**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Candidates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>149</td>
</tr>
<tr>
<td>Blood Type O</td>
<td>69.8% (104)</td>
</tr>
<tr>
<td>CPRA ≥ 80%</td>
<td>63.1% (94)</td>
</tr>
<tr>
<td>Ethnicity- Black</td>
<td>16.1% (24)</td>
</tr>
<tr>
<td>Ethnicity- Hispanic</td>
<td>8.7% (13)</td>
</tr>
<tr>
<td>Age over 50</td>
<td>38.3% (57)</td>
</tr>
<tr>
<td>DD Waiting Time &gt; 1 year</td>
<td>75.2% (112)</td>
</tr>
<tr>
<td>Previous Kidney Transplant</td>
<td>58.4% (87)</td>
</tr>
<tr>
<td>Willing to accept a shipped kidney from any center</td>
<td>91.3% (136)</td>
</tr>
</tbody>
</table>
### Donor Characteristics

*Donors entered in August 2011 Match Run*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Donors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>158</td>
</tr>
<tr>
<td>Blood Type O</td>
<td>38.0% (60)</td>
</tr>
<tr>
<td>Age over 50</td>
<td>27.8% (44)</td>
</tr>
<tr>
<td>BMI over 30</td>
<td>17.1% (27)</td>
</tr>
<tr>
<td>Willing to ship a kidney</td>
<td>97.5% (154)</td>
</tr>
<tr>
<td>Willing to travel to any center</td>
<td>37.3% (59)</td>
</tr>
<tr>
<td>Non-directed donor</td>
<td>2.5% (4)</td>
</tr>
</tbody>
</table>
KPD Work Group Activities
# Operational Subcommittees

<table>
<thead>
<tr>
<th>Subcommittee</th>
<th>Description</th>
</tr>
</thead>
</table>
| Strategic Planning | • Create a vision, mission, set of values, measureable goals, and evaluation plan for the KPDPP  
                      • Look at the internal and external barriers to the program’s success, develop strategies to overcome these barriers, and develop a road map to reach these goals – both short and long term. |
| HLA              | Review unexpected positive crossmatches and recommend ways to prevent unexpected positive crossmatches in future match runs.                        |
| Financial        | In the short term, the subcommittee is developing KPD financial best practices and templates. The subcommittee is also discussing recommendations for the overall structure of financing for KPD. |
Revisions to KPD Operational Guidelines

In September, the Kidney Committee approved the following changes:

- Incorporation of previously approved donor chain language into Operational Guidelines
- Chain Cap Revision
- DP typing optional
- What to do when a chain breaks
The KPD Work Group is drafting KPD policy.

Some sections will apply to KPD in general; other sections will only apply to the OPTN program.

The goal is to have a proposal out for public comment in spring 2012.
KPD Automated Solution Update
Pre-Match Data Entry Screens

- Enter KPD application from UNet℠
- Add and maintain donors and candidates
- Search for donors and candidates
- Verify ABO
- Print records
Progress on Pre-Match Data Entry Screens

- Training will occur in December 2011.
- The system will be available to KPD Pilot Program participants by the end of 2011.
ABo Pending Candidates

To verify the ABO, click the candidate’s KPD ID below. The ABO must be verified by a second user before the candidate can be eligible for KPD match runs.

<table>
<thead>
<tr>
<th>KPD Candidate ID</th>
<th>Name</th>
<th>SSN</th>
<th>Center</th>
<th>Add Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>200135</td>
<td>Bunny, Bugs</td>
<td>555-44-7777</td>
<td>COUC-TX1</td>
<td>9/23/2011</td>
</tr>
<tr>
<td>200129</td>
<td>Man, Bat</td>
<td>555-44-5555</td>
<td>COUC-TX1</td>
<td>9/15/2011</td>
</tr>
<tr>
<td>200127</td>
<td>Simpson, Homer J</td>
<td>333-22-1111</td>
<td>COUC-TX1</td>
<td>9/13/2011</td>
</tr>
</tbody>
</table>

Total: 5
Candidate name: Simpson, Homer J
KPD candidate ID: 200127
Waitlist ID: 683809

Candidate Summary

Candidate Choices

INSTITUTION
Home transplant center: COUC-TX1

KPD CANDIDATE CHOICES

Candidate willing to travel? *

If so, to which center(s) is the candidate willing to travel? R

Available options:
- All centers
- Any center within 50 miles
- Any center within 100 miles
- Any center within 250 miles
- Any center within 500 miles
- ALUA-Univ of Alabama Hospital
- ARBH-Baptist Medical Center
- ARCH-Arkansas Children’s Hospital
- ARUA-UAMS Medical Center
- AZCH-Phoenix Children’s Hospital

Yes ☐ No ☐
Future Functionality

- Eligibility processing
- Display of match results
- Tracking of matches
- Candidate and donor history
- Post-match reports
- Integration with other applications
Questions